STIMULATION CIRCUITRY AND CONTROL OF ELECTRONIC MEDICAL DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims priority from US Provisional Patent Application 60/426,182, filed November 14, 2002, entitled, "Stimulation circuitry and control of electronic medical device," which is assigned to the assignee of the present application and is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to electronic medical devices, and specifically to devices and methods for safely exposing patients with implanted medical devices to RF energy.

BACKGROUND OF THE INVENTION

Magnetic resonance imaging (MRI) is a technique based on the principles of nuclear magnetic resonance that produces high quality images of the human body. During an MRI procedure, a patient is typically placed supine on a horizontal table that is moved through a large static magnetic field upon which are imposed rapidly changing and intense magnetic fields and pulses of radio frequency (RF) radiation. Detailed information on the interior of the body is obtained by computer analysis of the magnetic resonance produced by the rapidly changing electric and magnetic fields.

The presence of strong and rapidly changing RF and magnetic fields is often a limitation upon the use of MRI. These fields may induce significant current flow in wires, electrodes, and other conductive material located in the area of the imaging equipment, as well as those attached to or implanted within the patient. Such MRI-induced currents may interfere with the diagnostic quality of the MRI images or cause damage to the patient by, for example, unwanted heating of tissue in the vicinity of the conductive material. The use of MRI is therefore often limited in instances in which the patient has permanently implanted devices that are electromagnetically responsive to the applied fields.

US Patent 4,951,672 to Buchwald et al., which is incorporated herein by reference, describes a method to prevent the RF pulses in MRI from being converted to frequencies that would cause false readings in a patient whose ECG measurements are being taken

during MRI, and to protect the patient from undesired heating by selection of appropriate impedance in the lead wires.

US Patent 5,782,241 to Felblinger et al., which is incorporated herein by reference, describes a detector device for electrocardiograms incorporating nonmetallic electrodes that can be used while the patient is exposed to MRI.

US Patent 5,445,162 to Ives, which is incorporated herein by reference, describes a method of electroencephalogram (EEG) recording during MRI so that data can be attained that enable correlation between anatomical information and particular neurophysiological phenomena.

US Patent 6,032,063 to Hoar et al., which is incorporated herein by reference, describes a leadwire harness system used for recording an electrocardiogram (ECG) during MRI. The system includes a set of leadwires each having a nichrome wire helically wound on a bundle of glass or other high strength fibers and surrounded by an insulating jacket.

US Patent 6,178,353 to Griffith et al., which is incorporated herein by reference, describes a medical device having both an implanted portion and external (non-implanted) portion comprising permanent magnets, such as an implanted cochlear stimulator (ICS) system, designed so as to reduce the electrical energy absorbed by the device.

SUMMARY OF THE INVENTION

In embodiments of the present invention, apparatus for reducing undesired RF-induced effects on tissue of a patient with an implanted medical device having two or more conductive elements, comprises a low-resistance shunt adapted to be placed in parallel in a circuit defined by the conductive elements and tissue with which they are in contact. The electrical resistance of the shunt is typically substantially less than that of the tissue of the circuit, so that a substantial portion of the current generated in the circuit by the RF energy passes through the lower-resistance shunt instead of through the tissue. As a result, a substantial portion of the heat generated by the RF-induced current is dissipated at the location of the shunt instead of at the site of the tissue, such that the heat generated at the site of the tissue is generally insufficient to cause damage to the tissue. For some applications, the shunt is adapted for protecting against RF energy produced by imaging modalities, such as MRI.

In some applications, the shunt improves the quality of MRI images or of other

RF-mediated diagnostic modalities, such as by reducing or relocating eddy currents and/or by reducing the temperature of the tissue.

In some embodiments, the shunt comprises a switch, which is closed when the patient is exposed to RF energy, such as during an MRI procedure, thereby incorporating the shunt into the circuit. When the switch is open, the shunt is electrically removed from the circuit, allowing the implanted device to operate normally. Typically, the switch is configured so that its default setting is closed, and it is only opened when a procedure is being performed using the implanted device. When this configuration is used, the patient can generally be safely exposed to a source of RF energy, such as MRI, since the shunt is by default included in the circuit defined by the conductive elements and the tissue.

In some embodiments, the switch comprises an optical or an RF-operated switch, which enables the remote operation of the switch. In other embodiments, the shunt comprises a frequency-dependent resonant circuit, the impedance of which changes substantially when it is exposed to certain RF frequencies, such as those typically used in MRI. As a result, the shunt functions as a self-switching device, without the need for an externally-controlled discrete switch.

In some embodiments of the present invention, the techniques described herein are used in conjunction with methods and apparatus described in PCT Patent Publication WO 01/85094 to Shalev et al., which is assigned to the assignee of the present patent application and is incorporated herein by reference.

There is therefore provided, in accordance with an embodiment of the present invention, a method for use with an implanted medical device having two conductive elements in contact with tissue of a subject, the method including:

providing a first impedance between the conductive elements when the subject is exposed to a source of radiofrequency (RF) energy; and

providing a second impedance between the conductive elements, at least two times greater than the first impedance, when the subject is not exposed to the RF energy.

For some applications, providing the first impedance includes providing a resistance. Alternatively or additionally, providing the first impedance includes providing a capacitance.

For some applications, providing the first impedance includes providing an impedance less than 2000 ohms. For some applications, providing the second impedance

includes providing an impedance at least 4 times greater than the first impedance.

For some applications, providing the second impedance includes providing an impedance of at least 3000 ohms. For some applications, providing the first impedance includes providing an impedance at least 50% less than an impedance of the tissue.

In an embodiment, the tissue includes heart tissue of the subject and the conductive elements are in contact with the heart tissue, and providing the first impedance includes providing the first impedance between the conductive elements in contact with the heart tissue.

In an embodiment, the tissue includes tissue of a structure of the subject and the conductive elements are in contact with the tissue of the structure, the structure selected from the list consisting of: a sphenopalatine ganglion (SPG) of the subject, an anterior ethmoidal nerve of the subject, a posterior ethmoidal nerve of the subject, a communicating branch between an anterior ethmoidal nerve and a retro-orbital branch of an SPG of the subject, a communicating branch between a posterior ethmoidal nerve and a retro-orbital branch of an SPG of the subject, a greater palatine nerve of the subject, a lesser palatine nerve of the subject, a sphenopalatine nerve of the subject, a communicating branch between a maxillary nerve and an SPG of the subject, a nasopalatine nerve of the subject, a posterior nasal nerve of the subject, an infraorbital nerve of the subject, an otic ganglion of the subject, an afferent fiber going into the otic ganglion of the subject, an efferent fiber going out of the otic ganglion of the subject, a vidian nerve of the subject, a greater superficial petrosal nerve of the subject, a lesser deep petrosal nerve of the subject, a cranial nerve of the subject, a nerve to a bladder of the subject, a pudendal nerve of the subject, a nerve of an upper limb of the subject, and a nerve of a lower limb of the subject, and providing the first impedance includes providing the first impedance between the conductive elements in contact with the tissue of the structure.

In an embodiment, the tissue includes tissue in a head of the subject and the conductive elements are in contact with the tissue in the head, and providing the first impedance includes providing the first impedance between the conductive elements in contact with the tissue in the head. For some applications, the tissue includes brain tissue of the subject and the conductive elements are in contact with the brain tissue, and providing the first impedance includes providing the first impedance between the

conductive elements in contact with the brain tissue.

In an embodiment, providing the second impedance includes providing an open circuit between the conductive elements. For some applications, providing the open circuit includes providing the open circuit unless an override signal to provide a closed circuit is received. For some applications, providing the open circuit includes receiving a signal from a remote site, and providing the open circuit responsive to the signal. For some applications, the signal includes an infrared signal, and providing the open circuit includes providing the open circuit responsive to the infrared signal. For some applications, the signal includes an RF signal, and providing the open circuit includes providing the open circuit responsive to the radiofrequency signal.

In an embodiment, the source of RF energy includes a diagnostic imaging modality, providing the first impedance includes providing the first impedance when the subject is exposed to the imaging modality, and providing the second impedance includes providing the second impedance when the subject is not exposed to the imaging modality. In an embodiment, the imaging modality includes magnetic resonance imaging (MRI), providing the first impedance includes providing the first impedance when the subject is exposed to the MRI, and providing the second impedance includes providing the second impedance when the subject is not exposed to the MRI.

For some applications, providing the first impedance including providing the first impedance when the tissue is exposed to RF energy with a frequency greater than a threshold value no greater than the lowest frequency of RF energy generated by an MRI device generating the RF energy, and providing the second impedance includes providing the second impedance when the tissue is not exposed to RF energy with a frequency greater than the threshold value. For some applications, the threshold value is 5 MHz, and providing the first impedance includes providing the first impedance when the tissue is exposed to RF energy with a frequency greater than 5 MHz.

There is also provided, in accordance with an embodiment of the present invention, apparatus for use with an implanted medical device having two conductive elements in contact with tissue of a subject, the apparatus including a shunt, electrically coupled between the conductive elements, the shunt adapted to be in a first state when the subject is exposed to a source of radiofrequency (RF) energy, and adapted to be in a second state when the subject is not exposed to the RF energy, the shunt being

characterized such that in the first state the shunt has a first impedance, and in the second state the shunt has a second impedance at least two times greater than the first impedance.

In an embodiment, the conductive elements include electrodes.

In an embodiment, the shunt includes:

a impeding element, adapted to provide the first impedance when the shunt is in the first state; and

a switch, adapted to provide the second impedance by providing an open circuit between the conductive elements when the shunt is in the second state.

For some applications, the impeding element includes at least one resistor, adapted to provide at least a portion of the first impedance. Alternatively or additionally, the impeding element includes at least one capacitor, adapted to provide at least a portion of the first impedance. Further alternatively or additionally, the impeding element includes resistive material, adapted to provide at least a portion of the first impedance.

For some applications, the impeding element is adapted to have a surface area greater than a surface area of the conductive elements.

For some applications, the switch is adapted to provide the open circuit unless the switch receives an override signal to provide a closed circuit.

In an embodiment, the apparatus includes an external controller, adapted to remotely operate the switch, and the switch is adapted to be remotely operated by the external controller. For some applications, the switch includes an infrared-sensitive optical switch, and the external control is adapted to remotely operate the infrared-sensitive optical switch. For some applications, the switch includes a radiofrequency-operated switch, and the external control is adapted to remotely operate the radiofrequency-operated switch.

There is further provided, in accordance with an embodiment of the present invention, apparatus including a medical device including:

two or more conductive elements, adapted to be implanted in a subject and brought in contact with tissue of the subject; and

a shunt, electrically coupled between the conductive elements, the shunt adapted to be in a first state when the subject is exposed to a source of radiofrequency (RF) energy, and adapted to be in a second state when the subject is not exposed to the RF

energy, the shunt being characterized such that in the first state the shunt has a first impedance, and in the second state the shunt has a second impedance at least two times greater than the first impedance.

In an embodiment, the medical device includes a control unit, adapted to operate the medical device.

In an embodiment, the conductive elements include electrodes.

In an embodiment, the medical device is adapted to be implanted in a body of the subject. In an embodiment, the shunt is adapted to be implanted in a body of the subject.

In an embodiment, the conductive elements are adapted to be implanted in a body of the subject. For some applications, the conductive elements are adapted to be implanted in a heart of the subject. For some applications, the conductive elements are adapted to be implanted in a structure of the subject selected from the list consisting of: a sphenopalatine ganglion (SPG) of the subject, an anterior ethmoidal nerve of the subject, a posterior ethmoidal nerve of the subject, a communicating branch between an anterior ethmoidal nerve and a retro-orbital branch of an SPG of the subject, a communicating branch between a posterior ethmoidal nerve and a retro-orbital branch of an SPG of the subject, a greater palatine nerve of the subject, a lesser palatine nerve of the subject, a sphenopalatine nerve of the subject, a communicating branch between a maxillary nerve and an SPG of the subject, a nasopalatine nerve of the subject, a posterior nasal nerve of the subject, an infraorbital nerve of the subject, an otic ganglion of the subject, an afferent fiber going into the otic ganglion of the subject, an efferent fiber going out of the otic ganglion of the subject, a vidian nerve of the subject, a greater superficial petrosal nerve of the subject, a lesser deep petrosal nerve of the subject, a cranial nerve of the subject, a nerve to a bladder of the subject, a pudendal nerve of the subject, a nerve of an upper limb of the subject, and a nerve of a lower limb of the subject.

In an embodiment, the conductive elements are adapted to be implanted in a head of the subject. For some applications, the conductive elements are adapted to be implanted in a brain of the subject.

In an embodiment, the medical device includes a control unit, adapted to operate the switch.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic, pictorial illustration showing a circuit defined by an implanted medical device, tissue of a patient, and a shunt, in accordance with an embodiment of the present invention;

Fig. 2 is a schematic illustration of a stimulation device for electrically stimulating a site of a patient, in accordance with an embodiment of the present invention;

Fig. 3 is a graph illustrating a transfer function gain, in accordance with an embodiment of the present invention; and

Figs. 4 and 5 are schematic illustrations of circuits of an external unit and an internal unit, respectively, of an electrical stimulation device, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic, pictorial illustration showing a circuit 32 defined by an implanted medical device 30 and tissue 12 of a patient, in accordance with an embodiment of the present invention. Implanted medical device 30 comprises a control unit 10, a shunt 18, and two or more implanted conductive elements, such as electrodes 14, which are in electrical contact with tissue 12. Tissue 12 acts as a resistive element of resistance R_T in circuit 32.

When the patient is exposed to RF energy, such as during an MRI procedure or another RF-facilitated procedure, the RF energy acts as an AC voltage source 16 which induces current to flow in circuit 32. In the absence of shunt 18, if circuit 32 is open at device 10, a substantial portion of the induced current flows through tissue 12, which may result in injurious heating of the tissue. If circuit 32 is shorted at device 10, leads 24 of the electrodes generate heat, which may result in injurious heating of tissue 12 and/or tissue in contact with the leads. Exposure to the RF energy may also damage medical device 30.

Shunt 18 comprises an impeding element 26 having an impedance R_C, the element comprising, for example, resistive material, one or more resistors, one or more capacitors, or substantially any other material, component, or circuit known in the art to have an impedance. Typically, impeding element 26 has a impedance at least 50% less than the impedance R_T of tissue 12. For some applications, impeding element 26 has an

impedance of less than between about 500 and about 1000 ohms. Shunt 18 is connected to circuit 32 such that the shunt is in parallel with AC voltage source 16 and resistance R_C. Typically, shunt 18 is implanted in the patient at a site less sensitive to heat than tissue 12. Alternatively, shunt 18 is placed external to the patient, such as in a case attached to an external surface of the patient.

Resistance R_C of shunt 18 is typically substantially less than resistance R_T of tissue 12. Therefore, a substantial portion of the current induced by AC voltage source 16 flows through impeding element 26 of the shunt, instead of through tissue 12, thereby reducing possible harmful heating of tissue 12. Heat generated at impeding element 26 is generally not harmful, because of the placement of the shunt, as described hereinabove. Furthermore, for some applications, impeding element 26 is configured to have a surface area substantially larger than the surface area of electrodes 14. Thus, the total heat generated is distributed over a greater area, resulting in less heating of tissue in contact with impeding element 26. (The total heat generated is not necessarily equal to that which would have been generated in the absence of the shunt, in part because the amount of current generated may change because of the inclusion of the shunt in the circuit.)

In an embodiment of the present invention, shunt 18 further comprises a switch 20, which is closed when the patient is exposed to RF energy (such as during an MRI procedure or during another RF-facilitated procedure), thereby incorporating the shunt into circuit 32. When switch 20 is open, shunt 18 is electrically removed from circuit 32, allowing implanted device 30 to operate normally. For some applications, such as those in which a therapeutic procedure is applied on an intermittent and controlled basis, the switch is configured so that its default setting is closed, and it is only opened when it receives an override signal indicating the procedure is being performed using the implanted device. When this configuration is used, the patient can generally be safely exposed to RF energy, such as that generated by MRI, since the shunt is by default included in circuit 32. For some applications, control unit 10 is adapted to operate switch 20.

In an embodiment of the present invention, switch 20 is remotely operated by an external controller 22, which activates the switch and, for some applications, monitors the status of the switch. In this embodiment, switch 20 typically comprises an infrared (IR)-sensitive optical switch, an RF-operated switch, or an ultrasound-coupled switch. An optical switch generally does not experience interference from MRI, since MRI

procedures typically do not use IR radiation. When adapted for use with MRI, the RF-operated switch is configured to operate at frequencies outside of the range of frequencies used in MRI, so as to avoid interference with the MRI.

In another embodiment, shunt 18 comprises a self-activating frequency-dependent circuit configured such that its impedance drops significantly when the circuit is exposed to certain RF frequencies, such as those typically used in MRI. As a result, shunt 18 functions as a self-switching device, without the need for an externally-controlled discrete switch. Typically, when exposed to RF frequencies in the frequency range not included in that of interfering electromagnetic energy, shunt 18 has an impedance at least 4 times greater than its impedance when exposed to RF frequencies in the frequency range of interfering electromagnetic energy. By way of illustration and not limitation, since the RF frequencies currently used in MRI and some other RF-facilitated diagnostic modalities are typically in the range of 20-150 MHz, the shunt may comprise an appropriate combination of resistance, inductance, and capacitance such that its impedance drops substantially above a certain lower frequency, such as 5 MHz. When exposed to RF frequencies in the interference frequency range, shunt 18 typically has an impedance equal to less than about 50% of the impedance of the tissue that it is adapted to stimulate, as may be measured between two poles of the electrodes of device 30. When not exposed to RF frequencies in the interference frequency range, shunt 18 typically has an impedance equal to greater than about 150% of the impedance of the tissue that it is adapted to stimulate, as may be measured between two poles of the electrodes of device 30.

Implanted device 30 is suitable for use in substantially any site in the body, including, but not limited to, the heart, the brain, and the head. For some applications, the device 30 comprises a pacemaker, a neural stimulator, a cranial nerve stimulator, a stimulator of the otic ganglion or the sphenopalatine ganglion or associated neuroanatomical structures, or a stimulator of peripheral nerves. In some embodiments of the present invention, the techniques described herein are used in conjunction with methods and apparatus described in the above-cited PCT Patent Publication WO 01/85094 to Shalev et al.

Fig. 2 is a schematic illustration of a stimulation device 100 for electrically stimulating a site of a patient, in accordance with an embodiment of the present invention. Stimulation device 100 comprises an external unit 60, an implanted unit 40, and one or more electrodes 50, either electrically coupled to implanted unit 40 over one or more

leads 48, or integrated directly into circuitry of implanted unit 40. External unit 60 and internal unit 40 comprise a transmitter coil 62 and a receiver coil 42, respectively. Circuitry in external unit 60, described below, drives transmitter coil 62 to generate an electromagnetic field, which induces a voltage drop in receiving coil 42 that is used to power circuitry of implanted unit 40, as described below. For some applications, such as protection from MRI-generated RF energy, transmitting coil 62 and receiving coil 42 are both tuned to a frequency of between about 100 kHz and about 10 MHz, such as a frequency of 6.78 MHz. The wireless coupling of the external and internal units facilitates the long-term implantation of implanted unit 40, which generally remains inactive when not wirelessly driven by the external unit. For some applications, external unit 60 is temporarily placed in a vicinity of implanted unit 40 during a stimulation procedure, typically on an external surface of the body or in the mouth.

External unit 60 comprises a resonance circuit 64, an RF amplifier 66, a power supply 72, and an RF generator 74. Power supply 72 and RF generator 74 supply RF amplifier 66 with power and an RF signal, respectively. RF amplifier 66 amplifies the RF signal and outputs the amplified signal to resonance circuit 64, which drives transmitter coil 62 to generate the electromagnetic field. Typically, external unit 60 comprises a control unit, which drives the RF generator, power supply, and RF amplifier. Additionally, external unit 60 typically comprises an RF detector 68, which provides feedback for the induced current in the implanted circuit, and generates a feedback signal responsive thereto. The feedback signal is amplified by a feedback amplifier 70, which outputs an amplified feedback signal to control unit 76. The control unit passes the feedback signal through an analog-to-digital converter, and samples the converted signal using the CPU of the control unit.

It is to be understood that although the components of external unit 60 are shown in the figures as incorporated in an integrated unit, this is for the sake of illustration only. In some embodiments of the present invention, one or more of the components of external unit 60 are located in one or more separate units, coupled to one another and/or external unit 60 over wires or wirelessly.

Implanted unit 40 comprises a receiver coil 42, a resonance circuit 44, and an RF envelope detector 46. Receiving coil 42 is typically tuned to substantially the same frequency as transmitting coil 62. (Actual operating conditions are generally considered when tuning the coils during design and manufacture, since mutual inductance during use

may be significant.) Thus, when exposed to the electromagnetic field generated by transmitting coil 62, receiving coil 42 drives resonance circuit 44 to output an RF signal to RF envelope detector 46. RF envelope detector 46 performs signal conditioning, and drives electrodes 50 to apply a current to tissue of the site of the patient.

Reference is now made to Fig. 3, which is a graph 53 illustrating a transfer function gain, in accordance with an embodiment of the present invention. In an embodiment of the present invention, implanted unit 40 further comprises a low-pass filter 52 (Fig. 1). Fig. 3 shows an example of a transfer function gain produced by low-pass filter 52.

It is to be understood that although the components of implanted unit 40 are shown in the figures as incorporated in an integrated unit, this is for the sake of illustration only. In some embodiments of the present invention, one or more of the components of implanted unit 40 are located in one or more separate units, coupled to one another and/or implanted unit 40 over wires or wirelessly.

Stimulation device 100 is suitable for stimulating substantially any site in which electrodes 50 and near which implanted unit 40 can be implanted, including, but not limited to:

- a sphenopalatine ganglion (SPG) (also called a pterygopalatine ganglion);
- an anterior ethmoidal nerve;
- a posterior ethmoidal nerve;
- a communicating branch between the anterior ethmoidal nerve and the SPG (retro-orbital branch);
- a communicating branch between the posterior ethmoidal nerve and the SPG (retro-orbital branch)
- a nerve of the pterygoid canal (also called a vidian nerve), such as a greater superficial petrosal nerve (a preganglionic parasympathetic nerve) or a lesser deep petrosal nerve (a postganglionic sympathetic nerve);
- a greater palatine nerve;

- a lesser palatine nerve;
- a sphenopalatine nerve;
- a communicating branch between the maxillary nerve and the sphenopalatine ganglion;
- a nasopalatine nerve;
- a posterior nasal nerve;
- an infraorbital nerve;
- an otic ganglion;
- an afferent fiber going into the otic ganglion;
- an efferent fiber going out of the otic ganglion;
- a cranial nerve, such as a vagus nerve, a glossopharyngeal nerve, or a vestibulocochlear nerve;
- a nerve to the bladder;
- a pudendal nerve; and/or
- a nerve of an upper or lower limb.

In an embodiment, stimulation device 100 is used in conjunction with the techniques and/or apparatus described hereinabove with reference to Fig. 1.

Figs. 4 and 5 are schematic illustrations of a circuit 80 of an external unit and of a circuit 90 of an implanted unit, respectively, of an electrical stimulation device, in accordance with an embodiment of the present invention. Coil connection 82 of circuit 80 (Fig. 4) is typically connected to a coil similar to transmitting coil 62, described hereinabove with reference to Fig. 2. Coil connection 92 of circuit 90 (Fig. 5) is typically connected to a coil similar to receiving coil 42, described hereinabove with reference to Fig. 2. VCC_high and VCC_low (Fig. 4) typically have voltages of 7.2 and 0 volts, respectively.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are

not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.